REMARKS

The withdrawal of claims 21-30 from further consideration as being for a non-elected invention is respectfully traversed. The Examiner is correct in stating that the undersigned "advised that the claims were to be examined as composition claims"; however, this is not to be construed as non-election of claims 21-30 which should be examined along with claims 1-10.

The rejection of claims 2-10 under 35 USC 1.75(c) as being of improper dependent form is obviated by the above amendment.

The rejection of the claims on the ground of double patenting over US 5,455,237 is respectfully traversed. The Examiner states:

> "*---Claims 1-10 are rejected under 35 USC 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 5,455,277. This is a double patenting rejection.---The preamble of the present claims has not been given any weight---*".

It is respectfully submitted that U.S. Patent No. 5,455,277 and the present claims do not "claim the same invention". Claim 1 of U.S. Patent No. 5,455,277 reads as follows:

> "*---A mosquito insecticidal composition comprising a mosquito insecticidally effective amount of a compound having one of the formulae: --- wherein:* R_1 *–*R_6 *may be the same or different and are alkyl having from 1 to 5 carbon atoms or hydrocarbyl aralkyl having up to 12 carbon atoms;*
>
> R_7 *is H, alkyl having from 1 to 12 carbon atoms, hydrocarbyl aryl or hydrocarbyl aralkyl each having up to 12 carbon atoms;*
>
> *m is an integer from 3 to 6, inclusive;*
>
> *n is an integer from 3 to 6, inclusive; or*
>
> *a salt thereof with an acid and a carrier therefor.* ---" (emphasis added).

Present claim 10 reads:

> "---A pharmaceutical composition for the treatment of hypertension
>
> comprising an effective anti-hypertensive amount of at least one compound in

association with a pharmaceutically acceptable , substantially non-toxic carrier or excipient; said compound having one of the formulae ---

wherein:

R and R' may be the same or different and are H, alkyl or aralkyl having from 1 to 12 carbon atoms;

R_1 –R_6 may be the same or different and H, R or R';

R_7 is H, alkyl having from 1 to 12 carbon atoms, hydrocarbyl aryl or hydrocarbyl aralkyl each having up to 12 carbon atoms;

m and n may be the same or different and are integers from 3 to 10, inclusive;

a-e may be the same or different and are integers from 3 to 10, inclusive; or

a salt --- with a pharmaceutically acceptable acid---" (emphasis added).

First, it is noted that it is not only the "preambles" of the respective claims that are different. The claims also differ in the structural formulae set forth in the claims.

Secondly, it is improper for the Examiner to "not give any weight to the preamble of the claims". In addition to the above-noted difference between the structural formulae of the respective claims, there exists another difference between the two. Thus, whereas US 5,455,277 describes compositions comprising polyamines useful as mosquito insecticides, the present claims are drawn to compositions adapted for the treatment of hypertension, a utility not disclosed by the patent.

More importantly, US 5,455,277 does not disclose an amount "effective for the treatment of hypertension". Inasmuch as the latter is an essential element of the invention and is a positive limitation recited in the claim, it is not seen how the claim can be rejected over prior art that does not disclose or remotely suggest the treatment of hypertension.

Any attempt by the Examiner to simply state that an "intended use" limitation renders a claimed composition obvious under 35 USC 103 overlooks, however, the recitation in the

claims of an amount of the polyamine effective to render the composition useful to treat hypertension. Since Bergeron does not specify the amount of the polyamine required to treat hypertension it cannot be said to disclose or suggest the claimed composition. Nor is the fact that the "intended use limitation" is in the preamble of the claim dispositive of the issue since the claim preamble has the import that the claim as a whole suggests for it. In other words, when the claim drafter chooses to use *both* the preamble and the body to define the subject matter of the claimed invention, the invention so defined and not some other is the one the patent protects. It is true that the preamble may be denied the effect of a limitation where the claim, apart from the introductory clause, completely defines the subject matter of the invention, and the preamble merely states a purpose or intended use of that subject matter. On the other hand, in those cases where the preamble to the claim is expressly or by necessary implication given the effect of a limitation, the introductory phrase must be deemed essential to point out the invention defined by the claim. Attention is directed to the decisions in *In re Paulsen,* 31 USPQ2d 1671; *In re Stencel,* 4 USPQ2d 1071; *Applied Materials, Inc. v. Advanced Semiconductor Materials,* 40 USPQ2d 1481 and *Kropa v. Robie et al,* 88 USPQ *478.*

In any event, the body of each of the claims defines an "an amount" of the polyamine sufficient to treat hypertension. This is a limitation of the claims which cannot be ignored. The Examiner will not be able to demonstrate that US 5,455,277 is even aware that the polyamines disclosed therein posses this utility much less teach an amount required to effect a therapeutic treatment..

Attention is also directed to the decision in *Ex parte Skuballa,* 12 USPQ2d 1570 (PTOBPAI, 1989) wherein USPTO Board expressly recognized the patentable distinction between claims drawn to compounds per se and claims drawn to pharmaceutical compositions containing the compounds. The decision also acknowledges that the phrase

"effective amount" is a critical limitation in a claim having a definite meaning which cannot simply be ignored.

Thus, the Examiner is left with the sole basis for the stated ground of rejection as the proposition that a pharmaceutical composition containing certain defined amounts of a chemical compound necessary for use of the composition for a stated purpose is inherently "obvious" and unpatentable over claims drawn to those chemical compounds. The proposition that claims drawn to pharmaceutical compositions containing defined amounts of a polyamine and a carrier are prima facie unpatentable over a reference claiming the polyamines is, of course, an untenable position. It is well settled that "compositions" are patentable. In *Ex parte Erdmann*, 194 USPQ 96 (PTOBA, 1975), this Board held that a known furanone compound combined with a carrier suitable to render the mixture useful as a herbicidal composition was patentable over a reference disclosing only the furanone. The Board stated:

> *"... We agree with the examiner that the mere recitation of a new use for an old composition does not render the composition patentable anew. However, the record before us does not establish that the claimed composition is old. There is nothing in the Ford et al reference which teaches that the furanone compound may be combined with a finely divided inert insoluble solid carrier vehicle ... "*

It is thus incontrovertible that the claimed composition comprising a polyamine in combination with a carrier is prima facie patentable over a reference which recites only the polyamines. Nowhere in any of the claims relied upon to reject the appealed claims is there even a hint as the amount of polyamine necessary to be effective to treat hypertension.

Attention is directed to the recent decisions in *Griffin v. Bertina,* 62 USPQ2d 1431 (Dec. April 2, 2002) and *Catalina Marketing. V. Coolsavings.com,* Fed. Cir. No. 01-1324 (Dec. May 8, 2002). In *Griffin*, Griffin filed an application claiming an invention directed to diagnosing thrombosis, a disease characterized by excessive blood clotting. Bertina filed an

application claiming a similar invention. The Board declared an interference between the two applications and designated the following count:

> "---*A method for diagnosing an increased risk for thrombosis or a genetic defect causing thrombosis comprising the steps of(A) obtaining, from a test subject, test nucleic acid comprising codon 506 within EXON 10 of the human Factor V gene; and (B) assaying for the presence of a point mutation in the nucleotides of codon 506 within EXON 10 of the human Factor V gene, wherein said point mutation correlates to a decrease in the degree of inactivation of human Factor V and/or human Factor Va by activated protein C, wherein the presence of said point mutation in said test nucleic acid indicates an increased risk for thrombosis or a genetic defect causing thrombosis*---".

The Board construed the count as requiring "an appreciation of the significance of a mutation at codon 506 within exon 10 of the human Factor V gene to the diagnosis of an increased risk of thrombosis due to a genetic defect". It then determined that, at best, Griffin's evidence "indicates that the Griffin inventors had identified a mutation of interest at an interesting place in a gene of interest in one affected patient". The Board concluded that the inventors did not recognize the significance of the discovery and thus did not have a reduction to practice of an invention defined by all the limitations of the count by that date.

The Board clarified Griffin's burden to establish reduction to practice as follows: "Griffin had to establish that it had actually made the invention described in the count, recognized it for what it was, and knew it would work for some practical purpose". It would have sufficed for Griffin "to show appreciation of a mutation that reliably correlated with APC resistance". Nevertheless, because it determined that Griffin's evidence failed to show that the Griffin inventors recognized a correlation between the point mutation and APC resistance, the Board concluded that Griffin did not show that it had reduced the invention to practice before Bertina and accordingly confirmed its award of priority to Bertina.

Griffin had argued, much like the Examiner herein would, that the count should be construed as limited only to its manipulative steps, i.e., obtaining test nucleic acid and identifying a point mutation in codon 5 06 within EXON 10 of the Factor V gene. Griffin

asserts that he and his co-inventor performed those steps before Bertina, and that they therefore reduced the count to practice prior to Bertina's priority date. Griffin argued that the count is not limited by the language "for diagnosing an increased risk of thrombosis or a genetic defect causing thrombosis" or by the "wherein" clauses directed to a correlation between the point mutation and decreased inactivation of Factor V by APC (i.e., increased APC resistance) because those clauses merely state the inherent result of performing the manipulative steps.

Similarly, in the present case, the Examiner would apparently argue that it is sufficient that US 5,455,277 discloses the polyamines employed in the claimed compositions, that they are 'capable of performing the intended use of killing mosquitos, and that , therefore, it meets the claim'.

Bertina responded to Griffin's argument that the intended use language and "wherein" clauses limit the count and require recognition of the correlation between the specific point mutation and the decrease in inactivation of Factor V by APC. Bertina also argued that Griffin did not perform the manipulative steps because it did not use a "test subject" and because the "assaying" step requires prior knowledge of the point mutation. Bertina asserted that the Board correctly determined that Griffin did not show that the inventors appreciated that the invention worked for its intended purpose, viz., to diagnose an increased risk of thrombosis. The CAFC concluded:

> *"--- that the Board did not err in construing the count to be limited by the preamble. A preamble to a claim "has the import that the claim as a whole suggests for it." Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995). The preamble language in this case is directed to "diagnosing an increased risk for thrombosis or a genetic defect causing thrombosis." That aspect of the invention is again stated in the body of the count: "wherein the presence of said point mutation in said test nucleic acid indicates an increased risk for thrombosis or a genetic defect causing thrombosis." Diagnosis is thus the essence of this invention; its appearance in the count gives "life and meaning" to the manipulative steps. See Kropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 195 1) (stating that a preamble is limiting when it*

> *is "necessary to give life, meaning and vitality to the claims or counts"). Consideration of the preamble gives meaning and purpose to the manipulative steps in this case. The first step recites that the test nucleic acid should be obtained from a "test subject." In the absence of the preamble's stated objective to diagnose thrombosis, the term "test. subject" is empty language. What is one testing for, and who is a suitable subject? Similarly, without the preamble, "assaying for the presence of a point mutation" has no purpose. Obtaining nucleic acid and assaying for a point mutation alone are merely academic exercises. The preamble is thus a necessary limitation---Griffin failed to demonstrate successful reduction to practice because it had not appreciated the utility of the point mutation as actually correlating with an increased risk of thrombosis. See Estee Lauder, 129 F.3d at 593, 44 USPQ2d at 1614 ("[A] reduction to practice does not occur until the inventor has determined that the invention will work for its intended purpose."). Griffin only offered evidence concerning performance of the manipulative steps in which it was discovered that LS possessed the point mutation of the count. He did not demonstrate that the inventors diagnosed that LS had an increased risk of thrombosis based on their prior knowledge of a correlation between the point mutation and APC resistance. Rather, Griffin's evidence shows only that the inventors may have unearthed one data point in their pursuit to identify a genetic mutation that might correlate with an increased risk of thrombosis. The Board's factual determination that Griffin's activities did not meet the count was therefore supported by substantial evidence---".*

Applicant makes the same argument herein. US 5,455,277 does not recognize the therapeutic effect stated in the claims and does not disclose the effective amounts for effecting this result. Therefore the "intended use" language of the claims and the effective amounts recited in the rejected claim are material to the "structural difference between the claimed invention and the prior art (necessary)--- to patentably distinguish the claimed invention from the prior art".

In *Catalina,* the CAFC clarified the circumstances where preamble language stating an intended use may or may not be limiting. The Federal Circuit stated:

> *"---While there is no litmus test---past rulings have identified the following guideposts for identifying limiting preamble language:*
>
> *1) Jepson claiming shows an intent to use the preamble to define the invention;*
>
> *2) Dependence on a disputed phrase for antecedent basis indicates a reliance on both the preamble and the claim body to define the invention;*

3) The preamble is essential to understand limitations or terms in the claim body;

4) The specification underscores additional structure or steps as important; or

5) Clear reliance on the preamble during prosecution to distinguish claimed invention from the prior art transforms the preamble into a claim limitation---
"

It is respectfully submitted that the so-called "intended use" language herein meets all of the above requirements except 1). The "intended use" language, coupled with recited effective amounts required to enable that use are necessary to "understand the limitations and terms of the claim", are "underscored in the specification as important" and are relied on herein "as distinguishing the claimed invention over the prior art".

Accordingly, withdrawal of this ground of rejection is respectfully requested.

On the assumption that claims 21-30 would also be subject to rejection on the same ground (i.e., double patenting), applicant traverses such rejection for the reasons stated above. In addition, the reference relied upon by the Examiner does not disclose an "article of manufacture" as identified in claims 21-30.

Applicants have earnestly endeavored to place this application in condition for allowance and an early action to that end is respectfully requested.

Respectfully submitted,

Miles & Stockbridge P.C.

Dennis P. Clarke
Registration No. 22,549

DPC/maa

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Customer No. 000181

1751 Pinnacle Drive
Suite 500
McLean, VA 22102-3833
Tel: (703) 903-9000
Fax: (703) 610-8686